DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Xopenex
Docket No.: 99E-5116

JUN 23 2000

The Honorable Jon Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Acting Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,362,755, filed by Sepracor, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Xopenex, the human drug product claimed by the patent.

The total length of the regulatory review period for Xopenex is 1,458 days. Of this time, 824 days occurred during the testing phase and 634 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: March 30, 1995.

   The applicant claims February 28, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 30, 1995, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: June 30, 1997.

   FDA has verified the applicant's claim that the new drug application (NDA) for Xopenex (NDA 20-837) was initially submitted on June 30, 1997.

3. The date the application was approved: March 25, 1999.

   FDA has verified the applicant's claim that NDA 20-837 was approved on March 25, 1999.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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